DETAILED ACTION

Applicants' Request for Continuing Examination of August 25, 2009 and amendment of September 23, 2009, in response to the Final Rejection of February 25, 2009, are acknowledged. It is acknowledged that Claims 3 and 19 have been amended.

Claims 1-12, 14, 16, 19-29, 31-35 are pending.

Based on amendment of the claims and to correct prior errors in the Action of May 19, 2008, the following Restriction/Election requirement is set forth.

It is noted that the claim set of September 23, 2009 is improper because if fails to list original Claims 36-38 as cancelled.

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1 and 2, drawn to a cellular method for identifying a modulator of an AMP-activated protein kinase (AMPK) by assaying LKB1 activity.

Group II, Claims 3-5 and 16, in full, and Claims 19-20, in part, drawn to an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition.

Group III, Claims 6-12, drawn to a cell capable of expressing LKB1, STRAD, and MO25 polypeptides.

Group IV, Claim 14, drawn to a cellular method for making a composition comprising LKB1, STRAD, and MO25 polypeptides.

Group V, Claims 19-20, in part, drawn to a method for identifying LKB1 activity modulators using an intracellular composition comprising LKB1, STRAD, and MO25 polypeptides.

Group VI, Claims 21, 22, 31, and 32, drawn to a kit comprising LKB1, STRAD, and MO25 polypeptides.

Group VII, Claims 23 and 24, drawn to a method for over-expressing an LKB1.

Group VIII, Claims 25 and 26, drawn to a method for identifying a MO25 binding partner.

Group IX, Claims 27 and 28, drawn to a method for identifying a MO25 genetic defect in PJS.

Group X, Claim 29, drawn to a method for identifying a modulator of an AMPK by assaying AMPK activity.

Group XI, Claims 33 and 34, drawn to an LKB1 substrate.

Group XII, Claim 35, drawn to an antibody.

This application contains claims directed to more than one sub-invention of the generic invention. The sub-inventions are as follows.

For Group I

- Elect one specific AMPK (SEQ ID NO:) encompassed by Claims 1 and 2.
- Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 1 and 2.
- Elect one specific LKB1 substrate encompassed by Claims 1 and 2.
- Elect one of (i) without STRAD or MO25, (ii) with STRAD only, (ii) with MO25 only, (iii) with STRAD and MO25.

Based on the election of (i)-(iii), above, elect one specific STRAD (SEQ ID NO:) and one specific MO25 (SEQ ID NO:) encompassed by Claims 1 and 2.

For Group II
- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- Elect one specific substrate (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.

For Group III
- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 6-12.

For Group IV
- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claim 14.

For Group V
- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 19-20.

For Group VI
- Elect one specific LKB1 (SEQ ID NO:), one specific STRAD (SEQ ID NO:), one specific MO25 (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.
- Elect one of (i) no AMPK polypeptide or polynucleotide, (ii) a specific AMPK polypeptide (SEQ ID NO:), or (iii) a specific AMPK polynucleotide (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.

For Group VII
- Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 21, 22, 31, and 32.
- Elect one specific MO25 (SEQ ID NO:) encompassed by Claims 25 and 26.

For Group IX
- Elect one specific parent MO25 (SEQ ID NO:) encompassed by Claims 27 and 28.

For Group X
- Elect one specific AMPK (SEQ ID NO:) encompassed by Claim 29.
- Elect one of (i) metformin, (ii) phenformin, or (iii) AICA riboside.

For Group XI
- Elect one specific substrate (SEQ ID NO:) encompassed by Claim 29.

For Group XII
- Elect one specific antigen (SEQ ID NO:) encompassed by Claims 33 and 34.

The inventions listed as Groups I-XII) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-XII appears to be that they all relate to the LKB1-mediated pathway. However, the LKB1-mediated pathway was known in the art. Moreover, Fryer et al, 2002 teach a method for identifying AMPK modulators, which anticipates Claim 29. Therefore Groups I-XII share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups II, III, VI, XI, and XII do not share a special common structural and functional feature while, the methods of Groups I, IV, V, and VII-X do not use the same reagents or produce the same results. In addition, the methods of Groups I, IV, V, and VII-X do not comprise all of the methods for making or using the products of Groups II, III, VI, XI, and XII. Accordingly, Groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Group II is the elected invention. The inventions listed as Group II relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they comprise the same or corresponding special technical feature, an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition. The products of Groups III, VI, XI, and XII are not so linked to Group II as to be encompassed by said single general inventive concept because said products do not share a common structure and function with the product of Group II. The methods of Groups IV, V, and VII-X are not linked so linked to Group II as to be encompassed by said single general inventive concept because said methods do not share the same modes of

operation, functions, or effects of the methods of Group II. For each of Groups II, III, VI, XI, and XII, the sub-inventions thereof do not share a common structure and function. II. For each of Groups II, IV, V, and VII-X, the sub-inventions thereof do share the same modes of operation, functions, or effects.

Based on prior election and prosecution, Applicants have elected Group II, drawn to an in vitro composition comprising LKB1, STRAD, and MO25 polypeptides and a method for identifying LKB1 activity modulators using said in vitro composition (for example, see the Office Action of May 19, 2008, pg 7, parg 4). Claims 1, 2, 6-12, 14, 21-29, 31-35 are withdrawn from further consideration as being drawn to non-elected subject matter.

In response to this communication, Applicants are required only to elect:

For Group II
- (A) Elect one specific LKB1 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- (B) Elect one specific STRAD (SEQ ID NO:), or one specific cell from which one specific endogenous STRAD can be isolated, encompassed by Claims 3-5, 16, and 19-20.
- (C) Elect one specific MO25 (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.
- (D) Elect one specific substrate (SEQ ID NO:) encompassed by Claims 3-5, 16, and 19-20.

Group II is directed to the above patentably distinct general of species. The species of (A) are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Likewise, the species of each of (B), (C), and (D) are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, for each of (A)-(D), for prosecution on the merits to which the claims shall be restricted if no generic claim

is finally held to be allowable. Currently, each of Claims 1, 2, 19, and 20 are generic with regards to one or more of (A)-(D).

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

If Applicants have any questions about this election requirement, they are welcome to contact the Examiner.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Should Applicants traverse on the ground that the inventions are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is requested that Applicants cite the serial number of the Application on every page of filed documents.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/
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